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Surveillance

CDC's HIV/AIDS surveillance system is the nation's source for key information used to track the epidemic. CDC funds and assists state and local health departments, which collect the information. Health departments in turn report their data to CDC so that information from around the country can be analyzed to determine who is being affected and why.

The ultimate surveillance goal is a nationwide system that combines information on AIDS cases, new HIV infections, and behaviors and characteristics of people at high risk so that CDC can track the epidemic and direct HIV prevention funding to where it is needed the most.

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Tracking AIDS Trends

During the 1980s, AIDS cases alone provided an adequate picture of HIV trends because the time between infection with HIV and progression to AIDS was predictable. This predictability, however, has diminished since 1996, when HAART became available. Access, adherence, and response to HAART affect whether or when HIV progresses to AIDS. Thus, trends in AIDS cases alone no longer accurately reflect trends in HIV infection. AIDS trends do, however, continue to provide important information about where care and treatment resources are most needed.

Tracking HIV Trends

By the year 2000, most, but not all, states had adopted some type of system for reporting HIV diagnoses to CDC. Tracking HIV trends is challenging and depends on several factors, such as how often people are tested, when during the course of their infection they are tested, whether and how test results are reported to health departments, and how case reports (with personal identifiers removed) are forwarded to CDC.

A major advance has been the development of the serologic testing algorithm for recent HIV seroconversion (STARHS). STARHS is a way of analyzing HIV-positive blood samples to determine whether an HIV infection is recent or has been ongoing. In 2001, an expert panel

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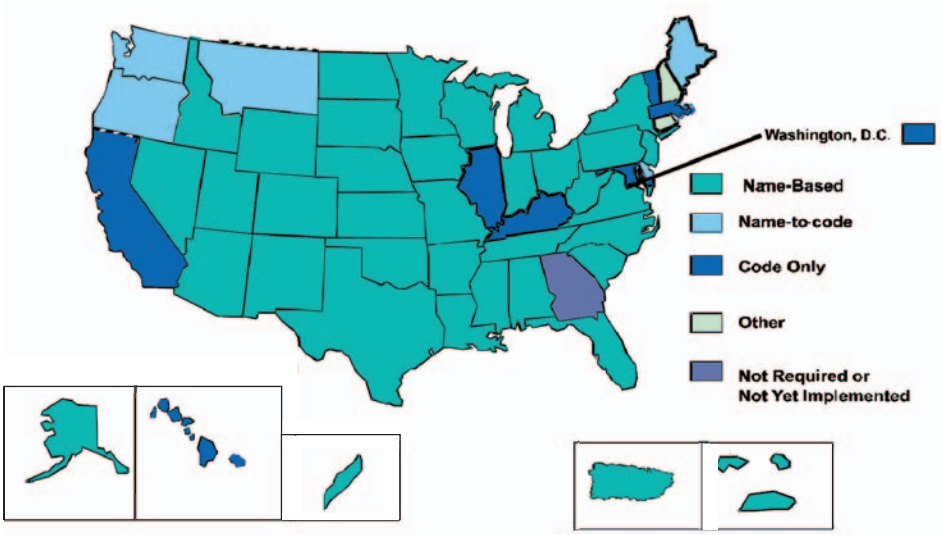
agreed that STARHS is the best method available for measuring new HIV infections. Since then, CDC has funded five sites (Alabama, Colorado, Michigan, New Jersey, and Seattle/King County in Washington state) to evaluate the use of STARHS. In 2004, a total of 34 states will add STARHS to their HIV incidence surveillance activities.

HIV Infection Surveillance, June 2003



Monitoring HIV Risk Behavior

Behaviors are monitored with regard to risk taking, HIV testing, care seeking, and adhering to treatment for HIV. CDC obtains behavioral information from several different populations.

General population

Several federal surveys collect information about HIV-related behaviors of the general population. They are conducted periodically so that trends can be evaluated. Here are a few examples:

- CDC conducts the Behavioral Risk Factor Surveillance System, the National Survey of Family Growth, and the National Health Interview Study.
- The National Opinion Research Center (University of Chicago) conducts the General Social Survey, with indirect CDC support.
- The Substance Abuse and Mental Health Services Administration conducts the National Survey on Drug Use and Health.

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People who are HIV-infected

SHAS (Supplement to HIV/AIDS Surveillance) is a CDC-supported project in which HIV-infected adults are interviewed about their sexual and drug-using behaviors, access to health care, HIV testing patterns, and HIV treatment (access, use, and adherence). Results are reported from 19 sites to state or local health departments. SHAS has been ongoing since 1990.

People who are at high risk for HIV

HITS (HIV Testing Survey) primarily interviews adults who are not HIV-infected but are at high risk for HIV infection. HITS collects information about what motivates people to get tested for HIV and what behaviors place people at risk for HIV. HITS has been conducted in 24 states since 1995.

A new behavioral surveillance system for populations at high risk is scheduled to begin in 2003. Conducted in 15 cities with high levels of AIDS, the new system will interview IDUs and MSM to determine their risk behavior, testing behavior, and use of prevention services. CDC expects to expand the system to include heterosexuals at high risk and to cover a wider geographic area.

Monitoring HIV Counseling and Testing Behavior

Since 1989, the HIV Counseling and Testing System has monitored use of CDC-funded HIV counseling and testing services. Through this system, each CDC-funded HIV counseling and testing episode is reported to CDC and includes information about demographics, self-reported behavior, and the HIV test result. Data from this system are used to guide the development of HIV prevention programs in response to the needs of the community. In 2004, the system will be expanded to include types and dates of referrals provided to clients with HIV-positive test results.

Prevention Programs

The primary component in CDC's fight against HIV/AIDS is HIV prevention programs. Programs consist of interventions intended to

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change risky behavior and improve the health of the people served. Interventions include encouraging early HIV diagnosis; delivering counseling, testing, and referral services; providing educational programs and materials; and training peers to be role models. They are delivered to individuals, groups, and communities in places such as storefronts, gay bars, health centers, housing communities, faith-based organizations, and schools. Street outreach techniques such as using mobile testing vans, offering incentives for participation or referral, and recruiting peers are some of the ways to reach as many people as possible.

CDC provides leadership, capacity-building assistance, and funding for programs at the state, local, and community levels. CDC funding supports staffing and running of programs, delivering interventions, and evaluating outcomes. In many cases, CDC requires that those who receive funding for programs (grantees) have a proven track record of providing effective programs. Less-experienced grantees may be funded for capacity building. CDC also strives to ensure that interventions meet local needs. Specifically, CDC asks that interventions be culturally competent; that is, they should be tailored to meet the cultural needs, expectations, and values of the populations they serve. Community planning helps ensure that priorities for HIV prevention are determined locally with input from affected communities and that they are consistent with scientific findings about what interventions are most effective for decreasing HIV transmission.

The primary component in CDC's fight against HIV/AIDS is HIV prevention programs.

Evaluation (to measure program effectiveness) is an important part of prevention programs. Programs funded by CDC are required to collect and submit evaluation data so that CDC can track and identify the most effective programs. CDC's evaluation efforts take several forms: (a) evaluation guidance outlining the types of data each funded health department must collect from its grantees, (b) regular reviews of each funded health department to evaluate effectiveness in community planning, and (c) ongoing reviews of funded CBOs.

In addition, CDC researches the effectiveness of HIV prevention interventions and the diffusion of these interventions. CDC's *Compendium of HIV Prevention Interventions with Evidence of*

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Effectiveness describes interventions that have proven effective with various groups. The REP (Replicating Effective Programs) project takes proven interventions and packages them in a tool kit for distribution. CDC's DEBI (Diffusion of Effective Behavioral Interventions) project then looks at ways to get these effective interventions to a broader audience.

Health Departments

CDC funds and works with 65 state, local, and territorial health departments to support prevention efforts and programs for people living with HIV and people at risk for HIV. All 65 health departments provide HIV counseling and testing services, which include referral and partner notification. A requirement for CDC funding is the development of a community planning process, which unites health departments and community members in developing an HIV prevention plan that reflects their local epidemic and guides HIV prevention efforts in their local area. Health departments also use CDC funds to support CBOs (indirect funding).

Community-based Organizations

CDC supports community-based, faith-based, and other nongovernment organizations in building partnerships for HIV prevention. These efforts provide interventions for populations at high risk, including people of color, MSM, substance abusers, and correctional facility inmates. They also provide HIV counseling and testing services and programs for people living with HIV/AIDS, to help them access prevention and treatment services.

Public-Private Partnerships

CDC works with business and labor groups to enhance the health, productivity, and well-being of workers and their families living with, affected by, or at risk for HIV/AIDS. The Business Responds to AIDS (BRTA) and Labor Responds to AIDS (LRTA) programs are worldwide public-private partnerships that serve as a resource to business and labor on a full range of HIV/AIDS issues. These partnerships set up workplace and related programs that combat complacency and stigma and support community activism, volunteerism, and corporate philanthropy.

How Is CDC Responding?

Another CDC partnership is AIDS: Act Now! This public-private effort has a council of 50 members from business, faith-based, public health, and HIV communities and the media. In addition, 5 alliances focus on issues such as leadership, youth, media, HIV testing and clinical care, and internet technology. In total, CDC has obtained the support of more than 100 partners who volunteer their time to explore how they can use their resources, influence, and outreach capabilities to enhance HIV prevention efforts in communities most affected by HIV and AIDS. As communities of color disproportionately bear the effects of the epidemic, most activities under AIDS: Act Now! are directed toward these minority populations.

Prevention Strategies

Among CDC's strategies for HIV prevention are

- providing up-to-date scientific information through guidelines
- promoting early diagnosis of HIV infection
- addressing the unique prevention needs of persons who are HIV-infected
- building the capacity of health departments and CBOs to deliver effective prevention programs that reduce the risk for HIV transmission
- increasing the quality of HIV prevention programs through evaluation

Guidelines are written recommendations for health care providers in the public or private sector.

Guidelines

Guidelines are written recommendations for health care providers in the public or private sector. Guidelines are developed after consultations with health care providers, public health officials, patient advocates, and policy experts. They are based on evidence from available scientific sources; where evidence is incomplete, the *best practices* opinions of specialists in the field are used.

Revised Guidelines for HIV Counseling, Testing, and Referral (CTR) (2001)

The first CTR guidelines were published in 1986. In response to recent advances in HIV treatment and prevention, CDC consulted with partners and specialists nationwide to revise the guidelines in 1994. Then, after a massive effort to review all current scientific evidence,

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obtain recommendations, and reach agreement on recommendations, CDC published the Revised Guidelines for HIV Counseling, Testing, and Referral in 2001. Using an evidence-based approach, these revised guidelines advise providers of voluntary HIV CTR how to improve the quality and provision of HIV CTR. The guidelines underscore the importance of early knowledge of HIV status and of testing that is more accessible and available.

Revised Recommendations for HIV Screening of Pregnant Women (2001)

In 1995, the US Public Health Service issued guidelines recommending universal counseling and voluntary HIV testing of all pregnant women and treatment for those infected to prevent mother-to-child HIV transmission. Subsequently, mother-to-child HIV transmission declined dramatically. In 1998, a study by the Institute of Medicine found that mother-to-child HIV transmission was mainly caused by a lack of awareness of HIV status; and in 1999, CDC convened experts to discuss and comment on these findings. As a result of these meetings, the Institute of Medicine report, and public comment, the Revised Recommendations for HIV Screening of Pregnant Women were published in 2001. These revised guidelines strengthen the recommendation that all pregnant women be tested for HIV as part of routine perinatal care, while preserving a woman's right to make her own decisions about testing.

Recommendations for Incorporating HIV Prevention into the Medical Care of Persons Living with HIV

In 2003, the CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America developed recommendations to help clinicians incorporate HIV prevention into the medical care of HIV-infected individuals. The major components of these recommendations are

- screening for HIV transmission risk behaviors and sexually transmitted diseases
- providing behavioral risk-reduction messages in the office and referring for additional prevention interventions and other related services
- facilitating the notification and counseling of sex partners and needle-sharing partners of HIV-infected individuals

How Is CDC Responding?

Advancing HIV Prevention: New Strategies for a Changing Epidemic

Advancing HIV Prevention is designed to reduce barriers to early diagnosis of HIV. Begun in April 2003, Advancing HIV Prevention is a combined effort of CDC and other agencies (government and nongovernment). It is designed to reduce barriers to early diagnosis of HIV infection and increase access to quality medical care, treatment, and ongoing prevention services for people with HIV. It emphasizes the use of public health approaches already proven effective at reducing new infections and spread of disease. For example, it will emphasize appropriate routine HIV testing, identification of new cases, partner notification, and increased availability of ongoing treatment and prevention services for HIV-infected individuals and their partners.

Advancing HIV Prevention is designed to reduce barriers to early diagnosis of HIV.

This new initiative was created in response to several factors.

- Declines in new HIV infections have leveled off.
- Increases in sexually transmitted diseases and risk behaviors have led to a possible increase in new HIV infections.
- Not enough people know their HIV status.
- People who know their HIV status can protect themselves and their partners.
- A simple, rapid HIV test is now available.
- Opportunities for preventing mother-to-child HIV transmission are being missed.

Four new strategies will be used to advance HIV prevention.

Strategy 1. Make voluntary HIV testing a routine part of medical care.

Strategy 2. Start using new models for diagnosing HIV infections.

Strategy 3. Prevent new infections by working with HIV-infected individuals and their partners.

Strategy 4. Further decrease mother-to-child HIV transmission.

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Although Advancing HIV Prevention emphasizes voluntary HIV testing, it does not endorse mandatory testing. It is consistent with CDC's other prevention strategies such as the HIV Prevention Strategic Plan, the Serostatus Approach to Fighting the Epidemic, and the Revised Guidelines for HIV Counseling, Testing, and Referral. By focusing on proven prevention programs and by linking HIV-infected people with the services and care they need, CDC can continue to protect people's health and slow the HIV/AIDS epidemic.

Serostatus Approach to Fighting the HIV/AIDS Epidemic

Recognizing that because of treatment advances more people with HIV are living longer and healthier lives, CDC developed the Serostatus Approach to Fighting the Epidemic (SAFE).

SAFE is a strategy for people who are HIV-infected. Although services are critical for people who are not infected but are at high risk, these services may not address the unique needs of those who are infected.

SAFE is a strategy for people who are HIV-infected.

Through voluntary HIV counseling and testing, SAFE will try to reach everyone who is living with HIV, including those who do not yet know that they are infected. This is important because every new HIV infection is the result of transmission by an HIV-infected person. SAFE aims to increase the proportion of people who are aware of their infection from the current 75% to 95% and to encourage an additional 30,000 people per year to be tested for HIV.

CDC-funded projects will help communities improve referrals to care and prevention services. The following projects and studies are being used to advance SAFE:

- **Project HEART (Helping Enhance Adherence to Antiretroviral Therapy),** a clinic-based behavioral intervention for patients who have not previously received HAART
- **ARTAS (Antiretroviral Treatment and Access Studies),** case management to improve access to HAART for people who have just received a diagnosis of HIV
- **Partnership for Health (Safer Sex and Adherence Intervention for HIV Outpatient Clinics),** an intervention encouraging health care providers to promote safer sex and adherence to therapy among patients

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- **SUMIT (Seropositive Urban Men's Intervention Trial),** a behavioral intervention trial to reduce the risk for HIV transmission by HIV-positive MSM and to increase the number who inform their sex partners of their HIV-positive status
- **PHIPP (Prevention for HIV-Infected Persons Project),** 5 health department and CBO projects conducting interventions to reduce HIV transmission
- **INSPIRE (Interventions for HIV-Positive Intravenous Drug Users: Research and Evaluation),** a behavioral intervention to help IDUs decrease their risk for HIV, increase access to care, and increase adherence to HAART

Capacity Building

CDC recognizes that those organizations most effective at reaching people at risk for HIV may be smaller or newer organizations and that these organizations may not have the expertise and experience required to be federal grantees. Therefore, CDC funds experienced organizations to help less-experienced organizations build skills to apply for funding and run effective programs. CDC also provides capacity-building advice and services directly to its grantees.

The goal of CDC'S HIV prevention capacity building is to help individuals, organizations, and communities enhance and sustain their HIV prevention efforts.

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Capacity building is carried out through

- **technology transfer**—translating scientific research into programs and practice
- **technical assistance**—providing expert programmatic, scientific, and technical support to grantees
- **training**—building the knowledge, skills, and abilities of trainers and service providers to deliver effective HIV prevention interventions
- **skills building**—increasing the knowledge and ability of individuals to effectively set up and maintain HIV prevention interventions and programs
- **information dissemination**—sharing information through print materials, meetings, websites, and mass media

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CDC's capacity-building strategy for HIV prevention includes

- nationwide training for
  - HIV prevention counseling
  - partner counseling and referral
- a national capacity-building assistance program for CBOs
- a technology transfer project in which 3 types of interventions—behavioral, biomedical, and structural—are diffused to grantees and other partners

DEBI (Diffusion of Effective Behavioral Interventions) is an example of capacity building using technology transfer to diffuse behavioral interventions. DEBI will diffuse interventions (that have been identified in CDC's *Compendium of HIV Prevention Interventions with Evidence of Effectiveness*) into programs in 2 waves.

The first wave of interventions is already in place.

- **POL (Popular Opinion Leader).** Trusted, well-liked men who frequent gay bars are trained to initiate casual conversations with peers, during which they endorse safer sex behaviors. The intervention focuses on changing community norms to support safer sex behaviors.
- **VOICES/VOCES (Video Opportunities for Innovative Condom Education and Safer Sex).** Health educators meet with small groups of clinic patients, divided according to gender and ethnicity. Participants watch ethnically appropriate videos, develop prevention strategies appropriate for their culture, and role-play to practice new skills.
- **Community PROMISE (Peers Reaching Out and Modeling Intervention Strategies for HIV/AIDS Risk Reduction in their Community).** This intervention trains people from at-risk communities to be community advocates for their peers, acting as role models, sharing personal stories about risk-reduction efforts, and distributing risk-reduction supplies.
- **Mpowerment.** A group of paid staff, volunteers, and young MSM conduct formal outreach and hold meetings for small groups of young MSM. They discuss safer sex and build related skills, train others to conduct informal outreach, and run an ongoing publicity campaign.

How Is CDC Responding?

A second wave of interventions will follow. Plans call for diffusion of more behavioral interventions as well as structural and biomedical interventions.

Evaluation

To improve the quality of HIV prevention programs, CDC is focusing on results.

Program performance indicators

To evaluate results and to comply with the President's Management Agenda, CDC will incorporate program performance indicators into its cooperative agreements with HIV prevention providers. Measurable, valid, reliable program performance indicators that can be achieved with current resources are being developed. Beginning in 2004, all funded health departments will report on these indicators, and CDC will report on them for the nation. The indicators will focus on the following components of an HIV prevention program:

- Community planning
- Prevention activities
  - Counseling, testing, and referral services
  - Partner counseling and referral services
  - Prevention for HIV-infected persons
  - Health education and risk-reduction activities
  - Prevention of mother-to-child HIV transmission
- Evaluation of major program activities
- Capacity-building activities

PEMS (Program Evaluation and Monitoring System)

Scheduled to begin in early 2004, PEMS is a system for evaluating and monitoring

- community planning
- program processes
- program outcomes
- counseling, testing, and referral services
- program performance indicators

PEMS responds to the need to strengthen the capacity of CDC and its grantees for monitoring the epidemic, developing and implementing effective HIV prevention interventions, and evaluating prevention

To improve the quality of HIV prevention programs, CDC is focusing on results.

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program processes and outcomes. PEMS will be used by health departments and CBOs that are directly funded by CDC as well as by CBOs and other organizations that are indirectly funded by CDC.

Putting the indicators and PEMS into action

To help grantees report indicator and PEMS data, CDC will publish reporting guidelines and requirements in HIV prevention program announcements later in 2003. CDC will help individual health departments establish baseline and performance targets for the program performance indicators. CDC is also developing manuals outlining standards and protocols for grantees. Ongoing support in the form of training and technical assistance (including on-site) will be available to grantees. After the data are analyzed, reports on the processes and outcomes will be provided to health departments, CBOs, and other partners.

Research

Among its many HIV research activities, CDC is involved in research related to

- diagnostic tests
- microbicides
- vaccines

Diagnostic Tests

In November 2002, the Food and Drug Administration approved a simple, rapid HIV test. The OraQuick Rapid HIV-1 Antibody Test offers advantages over conventional HIV blood tests. Easier blood collection (from fingertip vs. vein) and faster results (20 minutes vs. a week) should appeal to people who dislike having blood drawn and the inconvenience of coming back for a second visit to get their results. OraQuick will also be useful for determining the HIV status of pregnant women in labor and of health care workers accidentally exposed to HIV-infected blood. OraQuick is approved as a diagnostic aid; it is not approved for screening blood donors. Positive OraQuick test results must be confirmed by using other tests.

How Is CDC Responding?

Unlike other antibody tests for HIV, OraQuick can be stored at room temperature and requires no special equipment. In January 2003, OraQuick was approved for use outside of traditional laboratory or clinical settings; that is, it can be used in doctors' offices and community and outreach settings. CDC and the Centers for Medicare and Medicaid Services are working with state and other health officials to make the test widely available and to help them use it properly. Before the test was approved, CDC was involved in studies of the test's accuracy (sensitivity and specificity) as well as how the test can be used in certain settings.

In April 2003, the FDA approved another rapid test, called Reveal. Reveal is classified as a moderate complexity test and therefore must be performed in a laboratory.

Microbicides

CDC is actively involved in research to identify and test potential HIV microbicides. Microbicides are gels, creams, or suppositories that can kill or neutralize viruses and bacteria. When applied in the vagina before sexual intercourse, they can protect against some sexually transmitted diseases. A safe, effective, and affordable microbicide against HIV could help prevent many new infections.

Thailand

CDC collaborated with the Thailand Ministry of Health and the Population Council to conduct Phases I and II (safety) clinical trials of Carraguard, a candidate vaginal gel microbicide, in HIV-negative women and heterosexual couples.

Botswana

CDC is collaborating with the Botswana Ministry of Health and the Population Council to develop a site for a Phase III (efficacy) clinical trial of Carraguard.

United States

CDC will collaborate with US partners to conduct preclinical (animals and laboratory) and Phases I and II clinical trials of potential new HIV microbicides. In its own laboratories, CDC is also examining the safety and efficacy of some microbicides against HIV.

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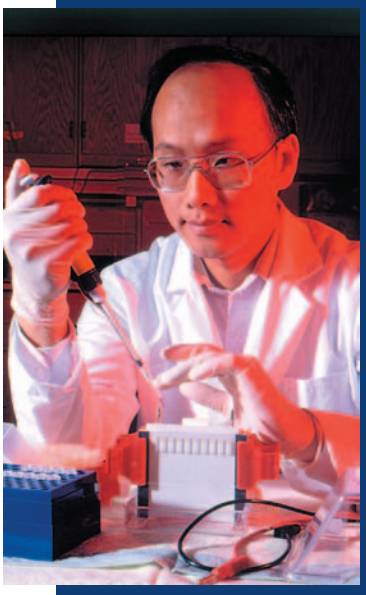

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Vaccines

The ultimate goal of everyone working to stop the HIV/AIDS epidemic is a vaccine to prevent infection. CDC is no stranger to vaccine development (considering its experience with other vaccines such as measles, hepatitis B, polio, and smallpox), but developing an HIV vaccine presents unique challenges. For example, it is critical that no one (whether involved in the studies or not) abandon safer sexual and drug-related behaviors proven to prevent HIV infection. Overall, vaccine development must not endanger progress already made in HIV prevention.

Until a vaccine is available, and even afterwards, we must continue to reinforce the already proven methods of HIV prevention.

CDC is actively involved in research to identify and test potential HIV microbicides.

CDC's HIV vaccine research focuses on conducting and evaluating HIV vaccine trials in the United States and elsewhere. Because different strains of HIV occur in different regions, several potential vaccines are being studied. A recent agreement between CDC and the National Institutes of Health provides exciting new opportunities for CDC to contribute more directly to Department of Health and Human Services vaccine development.

United States

CDC collaborated with a US vaccine developer, VaxGen, to test the efficacy of a vaccine (AIDSVAX B/B gp 120) at 61 sites, mostly in North America. CDC is also sponsoring extensive substudies (how the vaccine affects risk behavior and the virus itself) in Boston, Chicago, Ohio, San Francisco, and Seattle. In February 2003, VaxGen released initial vaccine trial results; HIV infection was not significantly reduced within the vaccinated study population as a whole (approximately 3.8% reduction rate). Further analyses of these results are in progress.

Thailand

CDC is also collaborating with VaxGen, the Bangkok Metropolitian Administration, and Mahidol University to test the efficacy of a vaccine (AIDSVAX B/E gp 120) in Bangkok. CDC helped develop counseling, educational, and prevention materials. CDC and the Thai government also identified individuals willing to participate

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and be followed up to evaluate risk behaviors and infection. CDC also worked with the community to build the understanding and support necessary for such a trial. CDC, Thai health officials, and VaxGen have ensured that participants receive appropriate risk-reduction counseling and are fully informed about how the trial works, the potential risks and benefits, and the importance of maintaining good risk-reduction behaviors during the trial. CDC also evaluates the clinical care, disease progression, and infectiousness of participants who become HIV-infected during the trial.

Africa

CDC is helping with preparations for HIV vaccine trials in West and East Africa. Along with Emory University and the National Institutes of Health, CDC is working to develop a vaccine (HIV-1 subtype A/G DNA+MVA) for people in West Africa. CDC is also collaborating with Ministries of Health and CDC international field stations in Côte d'Ivoire and Kenya to help them prepare for Phases I, II, and III (safety and efficacy) clinical trials.

Until a vaccine is available, and even afterwards, we must continue to reinforce the already proven methods of HIV prevention.